NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *ex rel.* JEFFREY D. FELDSTEIN, M.D., Plaintiff/Relator, v. ORGANON, INC., SCHERING-PLOUGH, INC., Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-CV-2690 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motions by Defendants, Organon USA Inc. (improperly pleaded as Organon, Inc.) ("Organon") and Schering-Plough Corporation (improperly pleaded as Schering-Plough, Inc.) ("Schering") (collectively "Defendants") to dismiss the Amended Complaint, to supplement the record, and for sanctions. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After carefully considering the submissions of the parties, and based upon the following, it is the finding of the Court that Defendants' motion to supplement the record is **granted**; Defendants' motion for sanctions is **denied**; and Defendants' motion to dismiss is **granted**.

I. BACKGROUND[1]

A. Factual Background

Plaintiff/Relator, Jeffrey D. Feldstein, M.D.'s ("Relator") *qui tam* action alleges that Organon intentionally withheld information from the FDA when it sought and eventually obtained FDA approval of Raplon®, a neuromuscular blocking agent. Organon is a pharmaceutical company which

[1] The facts set-forth in this Opinion are taken from the Parties' respective papers.

engages in the creating, manufacturing, distributing, and marketing of pharmaceuticals throughout the United States and abroad. In 2007, Schering purchased Organon. Raplon® was designed to paralyze a patient's throat area to allow the painless insertion of an endotracheal tube into a patient's trachea. An endotracheal tube establishes an airway to facilitate the administration of oxygen and anesthetic agents to patients during surgical or obstetric procedures. The FDA approved Raplon® on August 18, 1999. Soon after Raplon® became available, some patients suffered serious and sometimes fatal side effects which met the definition of serous adverse events ("SAE") as set forth in FDA regulations. After these adverse events began to be reported, Organon voluntarily withdrew Raplon® from distribution. The withdrawal of Raplon® took place on or about March 27, 2001.

On May 31, 2000, Organon hired Relator to serve as Associate Director of Medical Services for Antithrombotics. Relator's duties at Organon included assisting with the launch of a new drug, Arixtra, and developing post-marketing trials and research grants for Arixtra. During his tenure at Organon, Relator discovered that Organon personnel were concealing instances of bleeding associated with Arixtra from the FDA and the medical community. Relator alleges that his supervisor, Dr. Jonathan Deutsch, who was Organon's Director of Hospital Products, attempted to coerce Relator into disseminating information that would conceal the bleeding associated with Arixtra. Relator alleges that he was ultimately terminated because he refused to comply with Dr. Deutsch's demands.

Prior to his termination, Relator voiced his concerns about Arixtra to a colleague, Dr. Daniel Sack, who was Organon's Associate Director of Anesthesiology. During a discussion about Dr. Deutsch, Dr. Sack informed Relator about numerous SAEs and multiple deaths caused by Raplon® since its approval. Dr. Sack gave Relator an e-mail which Relator claims indicated that personnel at Organon knew prior to Raplon®'s approval by the FDA that Raplon® caused SAEs. This e-mail

was allegedly prepared by Dr. Deutsch and sent to Organon's Vice President of Medical Services, Dr. Deborah Shapse. The e-mail provides that "at the Dalla meeting [bronchospasm[2]] was heatedly discussed by the investigators, as a potential problem that needed to be addressed prior to [Raplon®'s] launch." The e-mail further notes that an Organon employee referred to as Cari is concerned and "that Medical Services needs to have a treatment protocol in place for bronchospasms prior to launch."

Based on Dr. Sack's e-mail and his belief that Organon tried to conceal information about Arixtra, Relator asserts that Organon took steps to conceal material information from the medical community and the FDA pertaining to Raplon®. Relator claims that in March or April of 2001, he contacted the FDA and informed them that he possessed evidence that Organon had suppressed information during Arixtra and Raplon's approval processes. In May of 2001, Relator met with two United States Attorney's, Nancy Rue and Roberta Brown, to discuss his allegations against Organon. Relator gave the Government a copy of Dr. Sack's e-mail. According to Relator, the Government expressed interest in his allegations but would not act until he commenced a suit under the False Claims Act. After his meeting with the Government officials, Relator continued to investigate and gather evidence.

B. Procedural Background

On April 4, 2002, Relator commenced this action by filing a *qui tam* Complaint under the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), against Organon and Akzo Nobel, Organon's then corporate parent, in the United States District Court for the District of Massachusetts. The complaint was filed under seal. In accordance with 31 U.S.C. § 3730(b)(4)(B), the United States was afforded 60 days, or until June 4, 2002, to decide whether to intervene. Beginning with its first motion filed

[2]A bronchospasm is a sudden constriction of the muscles in the walls of the bronchioles.

on May 21, 2002, the Government made thirteen separate applications for extensions of time, presumably so that it could investigate the allegations in Relator's Complaint and decide whether to intervene. On June 13, 2006, the Government elected not to intervene in this action.

Upon Relator's motion, on May 17, 2007, the District Court of Massachusetts ordered the case transferred to this Court. On February 11, 2008, the Honorable Mark Falk, U.S.M.J. unsealed the Complaint and ordered Relator to serve the Complaint upon the Defendants. On April 14, 2008, Relator filed an Amended Complaint and Jury Demand. Counsel for Organon and Schering were served with the Amended Complaint on April 17, 2008. Defendants filed a motion to dismiss on August 4, 2008. Defendants filed a motion to supplement the record on November 19, 2008, and a motion for sanctions on December 11, 2008.

II. DEFENDANTS' MOTION TO SUPPLEMENT THE RECORD

Defendants' seek to supplement the record in support of their motion to dismiss, with a sworn certification by Relator dated May 15, 2003 ("2003 Certification"), which was drafted in connection with another lawsuit filed against Organon. Defendants argue that the 2003 Certification directly contradicts a more recent certification by Relator submitted in opposition to Defendants' motion to dismiss.

A court has discretion to grant leave to supplement the record of a case. See Edwards v. Pa. Tpk. Comm'n, 80 F. Appx 261, 265 (3d Cir. 2003). In Edwards, the Third Circuit denied a motion to supplement the record because the moving party had waited until five months after discovery had closed to seek leave to supplement the record. Id. Here, Defendants submitted their reply to Relator's opposition in August 2008, but did not file their motion to supplement until November of 2008, several months later. Defendants have explained that they only recently discovered the 2003 Certification. Relator rebuts Defendants' explanation by informing the Court that the 2003

Certification was submitted as part of another action Relator filed against Organon, which means that Defendants had access to the 2003 Certification prior to filing their motion to dismiss. While this is technically true, Defendants explain that their current counsel was not involved in the other litigation.

Defendants argue that Relator would not be prejudiced if the 2003 Certification is allowed to be a part of the record. This argument is based on the fact that Defendants already knew about the 2003 Certification and had an opportunity to address the Certification in their brief in opposition to Defendants' motion to supplement the record.

Although Defendants' submission would have been more appropriate as a part of their original motion papers, the 2003 Certification is relevant regarding the issue of when and how Relator obtained information about Raplon®. Additionally, Relator has had an opportunity to address the certification and has used this opportunity to explain that the 2003 Certification is consistent with Relator's more recent certification. Because of the 2003 Certification's relevance and the fact that Relator will not be prejudiced, Defendants' motion to supplement the record is **granted**.

III. DEFENDANTS' MOTION FOR SANCTIONS

Defendants request sanctions against Relator pursuant to Fed. R. Civ. P. 11 and the Court's inherent authority. Defendants assert that Relator is abusing the judicial system and perpetrating a fraud on the Court because he has advanced factual allegations that Defendants believe are contradicted by the actual facts of this case. Defendants in large part rely on the 2003 Certification to support their contention that the actual facts of this case stand in contradiction to the facts as alleged by Relator.

> Rule 11 in pertinent part provides:
>
> b) Representations to the Court. By presenting to the court a pleading, written motion, or other paper--whether by signing, filing, submitting, or later advocating it--an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:
>
> (1) it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; [and]
>
> (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery[.]

Fed. R. Civ. P. 11(b)(1) and (3). "Rule 11 is intended for only exceptional circumstances." Gaiardo v. Ethyl Corp., 835 F.2d 479, 483 (3d Cir. 1987). "The legal standard for alleged violations of Rule 11 is reasonableness under the circumstances. Reasonableness is defined as an objective knowledge or belief at the time of the filing of a challenged paper that the claim was well grounded in fact and law." Amboy Banorporation v. Jenkens & Gilchrist, 2007 WL 2746832, at *5 (D.N.J. Sept. 14, 2007).

At issue here is whether a certification by Relator dated August 4, 2008 ("2008 Certification"), contains factual assertions that are unsupported by any evidence of record and are contradicted by the 2003 Certification. Although the 2003 Certification does seem to contradict the 2008 Certification, Relator has explained that the two certifications are in fact consistent. In the 2008 Certification, Relator explained that he initially learned of Defendants' alleged wrongdoing regarding Raplon® before he was terminated. In the 2003 Certification, Relator stated that he did not learn about Defendants' alleged wrong doing until after he was terminated. In his opposition to Defendants' motion to supplement the record, Relator explains that he did become aware of issues with the Raplon® approval process before he was terminated but only became aware of the extent of the wrongdoing thereafter.

The record at this point supports Relator's contention that he obtained information both before and after he was terminated. Nonetheless, based on the 2003 Certification, it appears that Relator did not learn that Defendants allegedly violated the law until after he was terminated. Although the 2008 Certification might be slightly misleading, Relator has clarified his assertions. Given Relator's candor and efforts to correct any ambiguities, and the fact that the 2003 Certification has been added to the record, this is not one of the rare cases where sanctions are warranted. Therefore, Defendants' motion for sanctions is **denied**.

IV. DEFENDANTS' MOTION TO DISMISS

Defendants have moved to dismiss Relator's Amended Complaint on the grounds that the Court lacks jurisdiction over this action because of previous disclosures to the public and allegations that Relator is not an original source; the Amended Complaint does not satisfy the heightened Fed. R. Civ. P. 9(b) pleading requirements for fraud claims; and Relator has failed to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Defendants also seek dismissal of Schering as a Defendant for failure to establish successor liability.

A. Standing

31 U.S.C. § 3730(e)(4)(A)(the "Public Disclosure Bar") "provides that no court has jurisdiction over a FCA *qui tam* action that is based on certain public disclosures unless the action is brought by an 'original source.'" United States ex rel. Mistick PBT v. Hous. Auth. Of the City of Pittsburgh, 186 F.3d 376, 378-9 (3d Cir. 1999) (quoting 31 U.S.C. § 3730(e)(4)(A)). Defendants argue that this Court lacks jurisdiction over this matter because Relator's action is based entirely on prior public disclosures and Relator is not an original source of the information at issue. For this reason, Defendants assert that Relator's Amended Complaint must be dismissed with prejudice pursuant to Fed. R. Civ. P. 12(b)(1) as barred by the Public Disclosure Bar.

When considering a motion to dismiss for lack of standing under Fed. R. Civ. P. 12(b)(1), a court must first determine if the challenge to jurisdiction is "facial" or "factual." Turicentro v. American Airlines, Inc., 303 F.3d 293, 300 n.4 (3d Cir. 2002). A "facial" challenge is brought when a defendant contends that a plaintiff has failed to properly allege jurisdictional facts in the complaint. Id. In contrast, a "factual" challenge is appropriate in situations where the facts underlying the complaint do not establish subject matter jurisdiction. "When resolving a factual challenge, the court may consult materials outside the pleadings, and the burden of proving jurisdiction rests with the plaintiff." Med. Soc'y of N.J. v. Herr, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) (citing Gould Elecs. Inc. v. U.S., 220 F.3d 169, 176, 178 (3d Cir. 2000)). When considering motions seeking dismissal for lack of jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1), "no presumpti[on of] truthfulness attaches to a plaintiff's allegations." Martinez v. U.S. Post Office, 875 F. Supp. 1067, 1070 (D.N.J.1995) (citing Mortensen v. First Fed. Sav. and Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977)). "Accordingly, unlike a Rule 12(b)(6) motion, consideration of a Rule 12(b)(1) motion need not be limited; conflicting written and oral evidence may be considered and a court may 'decide for itself the factual issues which determine jurisdiction.'" Id. (citing Williamson v. Tucker, 645 F.2d 404, 413 (5th Cir.) cert. denied, 454 U.S. 897 (1981)). Nonetheless, "[w]here an attack on jurisdiction implicates the merits of plaintiff's federal cause of action, the district court's role in judging the facts may be more limited." Martinez, 875 F. Supp. at 1071 (citing Williamson, 645 F.2d at 413 n.6). Once a Fed. R. Civ. P. 12(b)(1) challenge is raised, the burden shifts and the plaintiff must demonstrate the existence of subject matter jurisdiction. PBGC v. White, 998 F.2d 1192, 1196 (3d Cir. 1993).

i. Prior Public Disclosures

The FCA Public Disclosure Bar provides that:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). The Public Disclosure Bar applies where: (1) information was publicly disclosed via a source listed in § 3730(e)(4)(A); (2) the public disclosure included an "allegation or transaction" within the meaning of the statute; and (3) the complaint is "based upon" those disclosures. United States ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 519 (3d Cir. 2007). By its plain terms, the Public Disclosure Bar covers "allegations . . . from the news media." 31 U.S.C. § 3730(e)(4)(A). The statute also bars allegations filed as part of civil complaints. See, e.g., United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 334 (3d Cir. 2005) (holding that "a complaint in a civil action falls into the context of 'criminal, civil, or administrative hearings and is sufficiently public within the meaning of the [Public Disclosure Bar] to constitute a public disclosure").

In order to constitute 'allegations or transactions' within the meaning of the Public Disclosure Bar, the public disclosure must either allege the actual fraud, or must allege both the misrepresented state of facts and the true state of facts such that an inference of fraud may be drawn. Atkinson, 473 F.3d at 519. In fact, public disclosure of the material elements of a fraud claim has been found to be enough to bar a *qui tam* action even if the disclosure itself does not allege any wrongdoing. United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 572 (10th Cir. 1995); see also United States ex rel. Dingle v. BioPort Corp., 270 F. Supp. 2d 968, 977 n.1 (W.D. Mich. 2003), aff'd, 388 F.3d

209 (6th Cir. 2004).

The "based upon" component of the Public Disclosure Bar does not require that the publicly disclosed information be the actual and only basis of the relator's complaint. Rather, the relator's allegations "need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." Atkinson, 473 F.3d at 519 (quoting Mistick, 186 F.3d at 385-88). Notably, the Third Circuit has expressly held that the phrase "based upon" does not mean "actually derived from," because such an interpretation would render the original source exception superfluous. Mistick, 186 F.3d at 385-88.

Defendants suggest that Relator's action is based entirely upon allegations that were previously made in prior public disclosures. Specifically, Defendants argue that a comparison of the allegations in Relator's Amended Complaint with the allegations in other civil complaints and news media reports, all of which predate the inception of this suit, conclusively demonstrate that Relator's allegations are based upon those public disclosures and, therefore, fall squarely within the Public Disclosure Bar.

Defendants claim that the essence of Relator's Amended Complaint is the allegation that Organon wrongfully acquired FDA approval of Raplon® by misrepresenting, or failing to disclose to the FDA, Raplon®'s propensity to cause serious injury, and that doctors utilized Raplon® in reliance upon the FDA's approval and/or Organon's failure to disclose Raplon®'s risks. As a result of this alleged fraud on the FDA, Relator alleges, that the Government (i.e., Medicare and Medicaid) would not have paid claims for the use of Raplon®. Defendants assert that prior to the filing of this action on April 4, 2002, public disclosures revealed the same alleged misrepresentation and the same alleged true state of facts as asserted by Relator. Defendants detail that the allegations related to Raplon®'s adverse events were well-documented and publicized long before Relator filed this

action. In addition, well before Relator's filing, there was public disclosure of substantially similar allegations of fraud and cover-up of adverse event data. For example, the complaint filed in Rogers v. Organon, Inc. on February 20, 2002. The Rogers complaint alleged that Organon "failed to conduct adequate and appropriate studies which would have revealed that Raplon created a high risk of certain personal injuries and/or death and failed to provide any and/or adequate warnings concerning this risk." The Rogers complaint also alleged that Organon:

> was negligent in the design, manufacturing, testing, advertising, marketing, promotion, labeling, warnings given and sale of Raplon in that, among other things, it . . . (b) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the drug Raplon; . . . (f) Recklessly, falsely, and/or deceptively represented or knowingly omitted suppressed or concealed facts of such materiality regarding the safety and efficacy of Raplon® from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Raplon would never have been prescribed to plaintiff.

Indeed, the Rogers complaint described Organon's actions as constituting "knowing omissions, suppression or concealment of material facts, made with the intent that others rely upon such concealment, suppressions or omissions in connection with the marketing of Raplon." Moreover, the Rogers complaint alleged that "Defendant acted unlawfully and negligently, used or employed unconscionable commercial and business practices, engaged in deception, fraud, false pretenses, false promises or misrepresentations, and/or perpetrated the knowing concealment, suppression or omission of material facts with the intent that physicians and consumers including Plaintiffs, rely upon such concealment, suppression or omission, in connection with the sale or advertisement of Raplon." In further support of their position, Defendants cite the Spencer v. Organon, Inc. complaint filed on October 11, 2001, and the Payne v. Organon, Inc. complaint filed on November 28, 2001.

In response, Relator argues that his allegations are not substantially similar to the allegations contained in the complaints and articles discussed by Defendants. Relator further argues that the

complaints and articles discussed by Defendants do not set forth all of the essential elements of his claim.

Defendants and Relator agree that the essence of Relator's claim is that "Organon as a result of willful failure to disclose and/or through the use of fraudulent and/or deceptive information...caused many hospitals and physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid." Relator argues that the complaints submitted by Defendants contain "garden-variety negligence and strict liability claims arising from personal injuries that were allegedly caused by Raplon." Relator further argues that the cases and articles discussed by Defendants do not deal with his claim that Organon orchestrated a conspiracy to knowingly conceal SAEs from the FDA in order to again approval of Raplon®.

There is no controversy over whether the articles and cases identified by Defendants are sources listed in § 3730(e)(4)(A), nor that these public disclosures include allegations or transactions within the meaning of the Public Disclosure Bar. Newspaper articles are, by the statute's expressed terms, disclosures, and civil cases fall within the civil hearing category of permissible disclosures. Sorgnard, 396 F.3d at 334. At issue here is whether the claims and allegations in the public disclosures discussed by Defendants are "substantially similar" to those in the Amended Complaint.

The factual premise of Relator's opposition to Defendants public disclosure argument is in error. Defendants cite several forms of public disclosures at length. These passages clearly raise claims of knowing and/or intentional fraud and deception. For example, in claim (f) of his complaint, Rogers alleges that Organon:

> Recklessly, falsely, and/or deceptively represented or knowingly omitted suppressed or concealed facts of such materiality regarding the safety and efficacy of Raplon from prescribing physicians and the consuming public, and that had prescribing physicians and the consuming public known of such facts, the drug Raplon would never have been prescribed to plaintiff.

Relator is correct that the cases discussed by Defendants involve personal injury and do not seek return of money paid out by the Government through Medicare and Medicaid, however, this does not negate that the factual and legal underpinnings of the relief Relator seeks, and the relief sought in the personal injury cases identified by Defendants are the same.

Moreover, contrary to Relator's assertion, all elements of his fraud do not need to be previously disclosed, rather, only the material elements need to be disclosed. Sandia Corp., 70 F.3d at 572; see also BioPort Corp., 270 F. Supp. 2d at 977 n.1. The specific factual elements regarding Medicare and Medicaid have not been previously disclosed but these elements are not material to the fraud allegedly perpetrated on the FDA by Organon, and this is the fraud that underlies Relator's and the personal injury complainant's claims. Therefore, the allegations in Relator's Amended Complaint are "based upon" the "public disclosure" of "allegations" within the meaning of the FCA's Public Disclosure Bar. 31 U.S.C. § 3730(e)(4)(A).

ii. Original Source

An "original source" within the meaning of the FCA is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). The Third Circuit has explained that to be an original source, a relator "must have had (1) direct and (2) independent knowledge of the information on which the allegations are based and (3) have voluntarily [provided the] information to the Government before filing the action." Paranich, 396 F.3d at 335 (emphasis in original). "'Independent knowledge' is knowledge that does not depend on public disclosures. 'Direct knowledge' is knowledge obtained without any intervening agency, instrumentality or influence:

immediate." Atkinson, 473 F.3d at 520 (internal citations and some quotation marks omitted).

Defendants note that Relator at no time states that he had any personal involvement or familiarity with the FDA approval process for Raplon®. Plaintiffs argue that Relator failed to allege that he had direct and independent knowledge as to any Medicare and Medicaid claims submitted by the "many hospitals, physicians and/or patients." With regard to Relator's Medicare and Medicaid claim, Defendants assert that Relator cannot identify any entities or individuals by name, nor allege that he had personal contact with any of them. They argue that Relator is merely speculating that somebody, somewhere, somehow submitted illegitimate claims for reimbursement to the Government.

Defendants point to case law from other Circuit Courts which provide that independent knowledge "must not be derivative of the information of others, even if those others may qualify as original sources." United States ex rel. Fine v. Advanced Scis., Inc., 99 F.3d 1000, 1007 (10th Cir. 1996); See also United States ex rel. Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 703 (8th Cir. 1995) (citing United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160-61 (3d Cir. 1991)). Defendants turn to the Eighth Circuit for the proposition that "collateral research and investigations...[do] not establish direct and independent knowledge of the information on which the allegations are based within the meaning of § 3730(e)(4)(B)." Id. (internal citations and quotation marks omitted). Indeed, the Third Circuit has cautioned that "courts must be mindful of suits based only on 'secondhand information, speculation, background information or collateral research.'" Pa. Shipbuilding, 473 F.3d at 523.

Relator argues that a person possesses "direct" knowledge when he or she has obtained first-hand knowledge through his or her own efforts and not the efforts of an intermediary. Relator cites Haskins v. Omega Institute, Inc., for the proposition that "there is no requirement that a relator be

physically present during the alleged acts" because "evidence can be amassed through an independent investigation." 25 F. Supp. 2d. 510, 514 (D.N.J. 1998). Relator alleges that he is a direct independent source because he is an insider and a whistleblower who acquired an e-mail through his own efforts during the course of his employment with Organon and that he voluntarily provided this information to the Government. Relator also details his education and negative experience at Organon with Arixtra as support for his claim that he is an original source.

Defendants raise a factual challenge to the Amended Complaint. Defendants assert that the facts as pleaded establish that Relator does not have standing. Relator is not an original source of the information alleged in his Amended Complaint. Relator contends that an e-mail he obtained alerted him to the probability that Organon perpetrated a fraud on the FDA. Relator alleges that he obtained this e-mail as a result of his own investigation and that this is sufficient to satisfy the direct knowledge requirement. Relator misinterprets the direct knowledge element of the Public Disclosure Bar.

As a preliminary matter, Relator admittedly obtained the e-mail at issue after having a casual conversation with a colleague. During that conversation the colleague offered him the e-mail. The colleague giving the e-mail to Relator constitutes intervening agency, thus, defeating any claim that Relator is an original source. More importantly, Relator did not obtain substantial firsthand knowledge of wrongdoing. Relator explains that based on his education and his negative experience with Organon, he knew that the e-mail at issue meant that Organon committed fraud. The e-mail itself does not suggest such an inference. Relator has no first hand knowledge of the Raplon® FDA approval process and did not obtain any after the fact. Moreover, Relator's claim that Organon's fraud "caused many hospitals, physicians and/or patients to submit false reimbursement claims to Medicare and Medicaid" is speculative. Defendants are correct that Relator pleads no facts to

suggest that he is an original direct source of information that could possibly support his allegation. Furthermore, any information that Relator has obtained is secondhand and/or derivative.

The facts of record demonstrate that there has been a public disclosure of the information upon which Relator's claims are based, and Relator is not an original source of this information. Therefore, Relator does not have standing to pursue this action, and Defendants Fed. R. Civ. P. 12(b)(1) motion is **granted**.

B. Heightened Pleading

Although it has been demonstrated that Relator lacks standing, the Court will briefly address Defendants' Fed. R. Civ. P. 9(b) motion, which provides an alternate basis for dismissal. Rule 9(b) provides, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Under Fed. R. Civ. P. 9(b), a plaintiff alleging fraud merely needs to state the circumstances of the alleged fraud "with sufficient particularity to place the defendant on notice of the 'precise misconduct with which [it is] charged.'" Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007) (citing Lum v. Bank of America, 361 F.3d 217, 223-224 (3d Cir. 2004). "Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of ... [f]raud with all of the essential factual background that would accompany the first paragraph of any newspaper story - that is, the 'who, what, when, where and how' of the events at issue." In re Rockefeller Ctr. Props. Secs. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (citation omitted). "[R]ule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, [but] plaintiffs must use alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" Id. at 216 (quoting In re Nice Systems, Ltd. Sec. Litig., 135 F. Supp. 2d 551, 577 (D.N.J. 2001)). Moreover, "in applying Rule 9(b), courts should be 'sensitive' to situations in which 'sophisticated

defrauders' may 'successfully conceal the details of their fraud.'" Id. (quoting In re Burlington Coad Factory Sec. Litig, 114 F.3d 1410, 1418 (3d Cir. 1997).

Defendants argue violations of the FCA must be pleaded with particularity and that Relator's Amended Complaint fails to provide the necessary specifics. They claim that Relator has "failed to identify with particularity a specific false claim [submitted to the Government]." United States ex rel. Schmidt v. Zimmer, Inc., No. 00-1044, 2005 WL 1806502, *2 (E.D. Pa. July 29, 2005). Defendants explain that the Schmidt Court held that a *qui tam* complaint that alleges "simply and without any stated reason" a relator's belief that claims requesting illegal payment "must have been submitted, were likely submitted or should have been submitted to the Government" does not satisfy Fed. R. Civ. P. 9(b)'s heightened pleading standard. Id. at 3.

Defendants further argue that Relator's allegations regarding Defendant's alleged wrongful conduct lack specificity. Specifically, Defendants argue that Relator has failed to provide support for his allegation that Organon knowingly misrepresented and/or concealed relevant information from the FDA in order to obtain, and subsequently retain approval for Raplon®. Defendants argue that Relator has not identified any submissions to the FDA that contained misrepresentations or from which information was omitted. Defendants claim that they have been left without a clear understanding of the misconduct at issue in this case. Defendants contend that the only tangible evidence that Relator relies upon is an e-mail he obtained from a colleague and that the e-mail does not contain any information that would substantiate Relator's allegations and that the e-mail does not detail any information to authenticate it or determine its origin. Likewise, Defendants argue that Relator fails to provide any identifying information concerning the internal, non-public documents and Organon's various submissions to the FDA upon which he claims to rely. Additionally, Defendants argue that Relator cannot plead upon information and belief because such pleading is

not permitted in FCA cases where the relator is a corporate insider, which Relator claims to be and is. See United States ex rel. Bartlett v. Tyrone Hosp., Inc., 234 F.R.D. 113, 122 (W.D. Pa. 2006).

Relator argues that he has provided Defendants with adequate notice of his claim. He argues that the e-mail in question contains statements from which an inference can easily be drawn that Organon fraudulently concealed information from the FDA. Relator asserts that he has identified the individuals at Organon who sent, received, and were referenced in the e-mail. Relator argues that after receiving the e-mail, he subsequently learned that the investigators who participated in the US Phase III Pivotal trial for Raplon® had serious concerns about Raplon's propensity to cause SAEs in some patients. Relator further argues that any detail he has not provided is within the Defendants' sole control. Relator points to Eastern and Western District of Pennsylvania cases that reject overly stringent applications of Fed. R. Civ. P. 9(b). See Landsberg v. Levinson, 2008 WL 2246308 *3 n16 (W.D. Pa.); United States v. Kensington Hospital, 760 F. Supp. 1120, 1128-1126 (E.D. Pa. 1991). Landsberg specifically rejected Clausen v. Laboratory Corp. Of America, Inc, 290 F.3d 1303 (11th Cir. 2002), a case cited by Defendants, where the complaint was dismissed for failure to identify an actual claim illegitimately submitted to the Government. See Landsberg, 2008 WL 2246308 *3 n16. Landsberg however, is a public disclosure case, not a Fed. R. Civ. P. 9(b) case. Id. at *3 n .16. The Landsberg Court does detail in a footnote that it rejected Clausen but this dicta is not fully explained nor is the Third Circuit approach to Fed. R. Civ. P. 9(b). Id.

Relator does not address Schmidt, an Eastern District of Pennsylvania case that embraced Clausen and United States ex rel. Quinn v. Omnicare, 382 F.3d 432, 439-40 (3d Cir. 2004), which held the same as Clausen. Schmidt provided that a relator must identify specific illegitimate claims for reimbursement in order to substantiate a FCA claim. Schmidt, 2005 WL 1806502 at *2-3. Nonetheless, Relator's claim is that Defendants committed fraud when it obtained approval of

Raplon® and as a result, all claims for payments from the Government for Raplon® were illegitimate. The fraud at issue allegedly took place when Organon obtained approval for Raplon® and not when claims were submitted to the Government.

As discussed above, Relator's claim is based on an inference from an e-mail that Relator believes to be true because of his background and his negative experience with Organon concerning Arixtra. This does not provide the specificity required by Fed. R. Civ. P. 9(b). Relator assumes that Organon knew something and did not inform the FDA, however, Relator does not detail any concrete evidence that supports his allegations. Relator argues that he later learned that some investigators expressed concerns that Raplon® might cause SAEs but he does not explain why these investigators were concerned or what they did to follow up on these concerns or if their specific concerns were alleviated. Relator does not present any reports or test results or other documentation showing that Defendants knew Raplon® caused SAEs. The concerns of the investigators are unsubstantiated third party information that even if true are not sufficient to establish fraud. Relator's claim is highly speculative and insufficiently pleaded to satisfy Fed. R. Civ. P. 9(b). Therefore, Defendants' motion to dismiss is **granted**.

C. Defendants' Remaining Grounds for Dismissal

Defendants move to dismiss the Amended Complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6). Analysis of Defendants' Rule 12(b)(6) motion would be redundant because the Court has already dismissed Relator's Amended Complaint pursuant to Rules 12(b)(1) and (9)(b). Likewise, Defendants' successor liability motion does not require analysis as the Amended Complaint is dismissed as to all Defendants.

V. CONCLUSION

For the reasons stated, it is the finding of the Court that Defendants' motion to supplement the record is **granted**; Defendants' motion for sanctions is **denied**; and Defendants' motion for dismissal is **granted**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: April 6, 2009
Orig.: Clerk
cc: All Counsel of Record
Hon. Mark Falk, U.S.M.J.
File